



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/066,474 | 01/31/2002 | Charles A. Nicolette | GZ 2103.20 | 3508 |
| 30089 | 7590 | 10/21/2003 | EXAMINER | |
| GENZYME CORPORATION C/O MCCUTCHEN, DOYLE, BROWN, & ENERSEN MCCUTCHEN, DOYLE, BROWN & ENERSEN, LLP THREE EMBARCADERO CENTER SAN FRANCISCO, CA 94111 | | | RAWLINGS, STEPHEN L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1642 | 8 |
| DATE MAILED: 10/21/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/066,474

Applicant(s)

NICOLETTE, CHARLES A.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-29 are pending in the application and are currently subject to the following restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups I and II. Claims 1-7, 13-15, 19-21, and 27, insofar as the claims are a method for aiding in the diagnosis of a condition, wherein said method comprises determining the amount of expression of a MART-1 protein by detecting the amount of mRNA transcribing said protein using a probe or primer that is complementary to a sequence encoding a peptide selected from the group consisting of SEQ ID NO: 2 and SEQ ID NO: 25, and a diagnostic kit comprising said primer, classified in class 435, subclass 6 and class 536, subclass 24.3.

Groups II-XV. Claims 1, 7-10, 14, 17, 18, and 22-26, insofar as the claims are drawn to a method for aiding in the diagnosis of a condition, wherein said method comprises determining the amount of expression of a MART-1 protein by detecting the amount of said protein using an agent that specifically recognizes and binds to said protein, wherein said agent is an antibody or an antigen-binding fragment thereof, which has been prepared from an animal immunized with a peptide selected from the group consisting of SEQ ID NOs: 2, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, and 25, and a diagnostic kit comprising said agent, classified in class 435, subclass 7.1 and class 530, subclass 387.3.

Groups XVI-XXVIII. Claims 1, 7-10, 14, 16-18, and 22-26, insofar as the claims are drawn to an *in vivo* method for aiding in the diagnosis of a condition,

wherein said method comprises determining the amount of expression of a MART-1 protein by detecting the amount of said protein using an agent that specifically recognizes and binds to said protein, wherein said agent is an antibody or an antigen-binding fragment thereof, which has been prepared from an animal immunized with a peptide selected from the group consisting of SEQ ID NOs: 2, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, and 25, and a diagnostic kit comprising said agent, classified in class 424, subclass 1.49, for example, and class 530, subclass 387.3.

Groups XXIX-XLI. Claims 1, 7, 8, 9, 11, 12, 14, 22-24, and 26, insofar as the claims are drawn to a method for aiding in the diagnosis of a condition, wherein said method comprises determining the amount of expression of a MART-1 protein by detecting the amount of said protein using an agent that specifically recognizes and binds to said protein, wherein said agent is a cell that binds said protein, wherein said cell is an immune effector cell raised in the presence and at the expense of a peptide selected from the group consisting of SEQ ID NOs: 2, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21, 23, and 25, and a diagnostic kit comprising said agent, classified in class 424, subclass 7.24, for example, and class 435, subclass 372.1, for example.

Group XLII. Claims 28 and 29, drawn to an assay to screen for agents that modulate binding of MART-1 protein to its ligand, classified, for example, in class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:
The inventions in groups I-XLI are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions in groups I-XLII are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules

used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Claims 1, 3, 8, and 9-11 are linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is

Art Unit: 1642

(703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

1 Raw
STEPHEN RAWLINGS

slr
October 20, 2003